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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/258,947	03/01/1999	JONATHAN L. MILLER	011.00117	4588

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/20/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/258,947

Applicant(s)

Miller et al.

Examiner

G.R. Ewoldt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 6, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

1. Claims 9 and 11 are pending and being acted upon.
2. In view of Applicant's amendment and response, filed 1/06/03, the rejection under the first paragraph of 35 U.S.C. 112 for the introduction of new matter into the claims has been withdrawn.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 9 and 11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record as set forth in Paper Nos. 12, 16, and 22, mailed 11/20/00, 8/10/01, and 7/29/02, respectively.

Applicant arguments, filed 1/06/03, have been fully considered but are not found persuasive. Applicant argues that, "The specification as filed satisfies the written description requirement for the claims. In particular, page 22, lines 3-12 fully describes an isolated molecule capable of binding to an isolated peptide which comprises an amino acid sequence as shown in SEQ ID No:174."

It is the Examiner's position that the citation merely discloses the properties which the peptide of the claims should have - no actual peptides comprising the properties are disclosed.

Applicant asserts that "a large number of species are listed that define the claimed genus (see specification, page 17, line 23-page 18, line 15 and page 19, line 14-page 21, line 24). Each of the listed species of peptides is defined as meeting the limitations of the claims. Claim 11 is fully described on page 24, line 33-page 25, line 18."

It is the Examiner's position that the disclosure comprises no more than a list of peptides that might meet the limitations of the instant claims. Of all the disclosed peptides, only the peptide of SEQ ID NO:94 has been demonstrated to actually meet some of the limitations of the claims. None of the peptides have been shown to have "a three dimensional structure complementary to the three dimensional structure of the second peptide," as is required by Claim 9.

Applicant argues "To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the invention at the time the application was filed," and "An actual reduction to practice is not required."

It is the Examiner's position that these arguments, i.e., a reiteration of the Written Description Guidelines, add little to the patentability of the peptides of the instant claims. It remains the Examiner's position that while the specification discloses a method for determining whether the peptides of the instant claims exist, it discloses an insufficient written description of the claimed peptides themselves.

Applicant argues that "With particular respect to a claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through description of a representative number of species which have a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus."

The Examiner agrees with Applicant's position in this respect, however, it is the Examiner's position that an insufficient number of species have been disclosed to describe the potentially unlimited claimed genus of peptides.

5. Claims 9 and 11 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention, for the reasons of record as set forth in Paper Nos. 12, 16, and 22, mailed 11/20/00, 8/10/01, and 7/29/02, respectively.

Applicant arguments, filed 1/06/03, have been fully considered but are not found persuasive. Applicant argues that,

"The present application, as filed, adequately describes how to make and use the present invention. In particular, the specification describes a method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claims without requiring undue experimentation. Experimentation is permissible, if routine or if the specification provides a reasonable amount of guidance," and "The identification of such peptides which have this desired functional property can be routinely done using, for example, the methodology disclosed in the specification at page 38, line 13 through page 40, line 20."

It remains the Examiner's position that the specification has not adequately disclosed whether or not a significant number of the peptides that might be encompassed by claims can be made at all. The specification discloses only decapeptides; the claims however, recite peptides of as few as 5 amino acids (which would likely be too short to bind) as well as peptides of up to 40 amino acids (which could comprise significant, and unpredictable, secondary structure). Accordingly, it remains the Examiner's position that the production of the peptides of the instant claims must be considered to be highly unpredictable and requiring of undue experimentation. Additionally, as set forth above, no peptides comprising all of the limitations of Claim 9 are disclosed. Further, it is the Examiner's position that whereas the specification discloses a method that might be enabling for producing a peptide that meets the limitations of the claims, said disclosure does not enable claims drawn to an array of the peptides themselves that have not been shown to exist.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 11 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record as set forth in Paper No. 22, mailed 7/29/02.

Applicant arguments, filed 1/06/03, have been fully considered but are not found persuasive. Applicant argues that the amendment of 1/06/03 has obviated the rejection.

It is noted that the claim still does not result in an isolated peptide. Applicant is advised that a final step of "isolating" the claimed peptide might obviate the rejection.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. Papers should be faxed to Technology Center 1600 at 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600
March 18, 2002